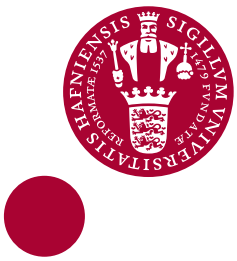

Statement on the conditions of use for health claims related to meal replacements for weight control

(Scientific Opinion)

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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Statement on the conditions of use for health claims related to meal replacements for weight control

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to provide a scientific opinion on the conditions of use for health claims related to meal replacements for weight control, and in particular to advise on whether a change in the conditions of use for claims on meal replacements for weight control regarding their micronutrient composition (i.e. referring to 30% of the Nutrient Reference Values (NRVs) laid down in Part A of Annex XIII of Regulation (EU) 1169/2011 instead of the 30% of NRVs laid down in Annex I of Directive 96/8/EC) would affect the conclusions reached by the NDA Panel on its Scientific Opinion with respect to the scientific substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417) and maintenance of body weight after weight loss (ID1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. Taking into account that the mechanisms by which meal replacements could exert the claimed effects were mostly related to their controlled energy content and the relatively high protein/low fat content, the Panel concludes that the differences in the micronutrient composition of meal replacements which would derive from changing the conditions of use from Directive 96/8/EC to Regulation (EU) 1169/2011 do not affect the scientific substantiation of health claims related to meal replacements for weight control and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006, as assessed by the Panel in 2010.

Keywords: meal replacements, weight control, health claims, conditions of use, micronutrients

Requestor: European Commission

Question number: EFSA-Q-2015-00579

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Summary

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to provide a scientific opinion on the conditions of use for health claims related to meal replacements for weight control, and in particular to advise on whether a change in the conditions of use for claims on meal replacements for weight control regarding their micronutrient composition (i.e. referring to 30% of the Nutrient Reference Values (NRVs) laid down in Part A of Annex XIII of Regulation (EU) 1169/2011 instead of the 30% of NRVs laid down in Annex I of Directive 96/8/EC) would affect the conclusions reached by the NDA Panel on its Scientific Opinion with respect to the scientific substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417) and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

The NDA Panel interpreted this mandate as a request for scientific advice on whether or not the conclusions reached by the Panel on the scientific substantiation of health claims related to meal replacement for weight control could be affected by a modification of the conditions of use which is limited to the micronutrient composition of meal replacements.

It is out of the scope of this mandate to advise on whether or not the conclusions reached by the Panel on the scientific substantiation of the above-mentioned claims could be affected by:

- changes in the energy content per serving as specified in EFSA's Scientific Opinion (i.e. a maximum of 250 kcal/serving).
- changes in the macronutrient composition of meal replacements as described in Annex I of Directive 96/8/EC;
- changes in target population(s) for the claims;
- new evidence on the relationship between the use of meal replacements and changes in body weight, e.g. human intervention (efficacy) studies which were not considered by the Panel for the scientific substantiation of such claims and which may have become available after the publication of EFSA's Scientific Opinion.

Switching from Directive 96/8/EC to Regulation (EU) 1169/2011 will imply some changes (increases or decreases) in the micronutrient content of meal replacements. These changes would be small (up to 13%) or absent for many micronutrients (i.e. vitamin D, thiamin, riboflavin, niacin, vitamin B6, folate, iron, zinc, copper, selenium). The content of the remaining micronutrients (i.e. vitamin A, vitamin E vitamin K, vitamin C, vitamin B12, biotin, pantothenic acid, chloride, calcium, phosphorus, iodine, magnesium, manganese, fluoride, chromium, molybdenum) would always be higher except for sodium, for which there are no NRVs in Regulation (EU) 1169/2011.

Taking into account that the mechanisms by which meal replacements could exert the claimed effects were mostly related to their controlled energy content and the relatively high protein/low fat content, the Panel considers that the differences in the micronutrient composition of meal replacements which would derive from changing the conditions of use from Directive 96/8/EC to Regulation (EU) 1169/2011 do not affect the scientific substantiation of health claims related to meal replacements for weight control and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 as assessed by the Panel in 2010.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Conditions of use of the health claims on meal replacement for weight control before Regulation (EU) No 609/2013

Directive 96/8/EC on foods intended for use in energy restricted diets for weight reduction[1] has laid down compositional and information requirements for products presented as a replacement for one or more meals of the daily diet, so called 'meal replacement for weight control'.

On the basis of EFSA's Scientific Opinion on the substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[2], two health claims are currently authorised for these products under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[3].

More specifically, in the Annex to Commission Regulation (EU) No 432/2012 establishing the list of permitted Article 13(1) health claims, the following two health claims are authorised:

- *'Substituting one daily meal of an energy restricted diet with a meal replacement contributes to the maintenance of weight after weight loss'.*
- *'Substituting two daily meals of an energy restricted diet with meal replacements contributes to weight loss'.*

In order to bear the claims, a food should comply with the specifications laid down in Directive 96/8/EC in relation to meal replacement for weight control. In order to achieve the claimed effect, depending on the claimed effect one or two meals should be substituted with meal replacements daily.

The changes introduced by Regulation (EU) No 609/2013

Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control[4] revises the legal framework applicable to foods for particular nutritional uses as set out in Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses[5] and the specific directives adopted under this framework including Directive 96/8/EC.

Regulation (EU) No 609/2013 does not include in its scope meal replacement for weight control products. This is because more and more foods intended for the general population have been placed on the market carrying similar statements which are presented as health claims for weight control as defined in Regulation (EC) No 1924/2006 and are authorised pursuant to that Regulation.

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[1] Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction, OJ L 55, 6.3.1996, p. 22, , as amended by Commission Directive 2007/29/EC of 30 May 2007, OJ L 139, 31.5.2007, p. 22

[2] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010, Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006, EFSA Journal 2010; 8(2):1466 19pp doi: 10.2903/j.efsa.2010.1466

[3] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9

[4] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulation (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35

[5] Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124, 20.5.2009, p. 21

In order to eliminate any potential confusion within this group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, the Regulation foresees that statements on such products should in the future be regulated solely under Regulation (EC) No 1924/2006 and comply with the requirements set out in the Annex of Regulation (EU) No 432/2012[6].

At this stage it is necessary to modify the conditions of use of two health claims related to meal replacements for weight control included in the list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health established by Commission Regulation (EU) 432/2012[7] pursuant to Article 13(3) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The currently applicable relevant conditions of use require compliance with the specifications laid down in Directive 96/8/EC in relation to food products under Article 1(2)(b) of that Directive. However, this Directive will be repealed by 20 July 2016 when Regulation (EU) No 609/2013 will revise the framework of Directive 2009/39/EC including Directive 96/8/EC. Reference to the legislation Directive 96/8/EC in the conditions of use of the two relevant claims needs to be replaced by inclusion of the explicit conditions of use.

When introducing the necessary technical changes consideration should be given to the nutrition reference values (NRVs) for vitamins and minerals requested for meal replacement for weight control by Directive 96/8/EC. According to Annex I of Directive 96/8/EC, meal replacement for weight control should provide 30% of NRVs laid down in that Annex.

It should be taken into account, however, that Regulation (EU) No 1169/2011 on the provision of food information to consumers[8] lays down in PART A of Annex XIII more recent NRVs for vitamins and minerals than those of Annex I of Directive 96/8/EC to which EFSA's Scientific Opinion and the current conditions of use of the claims on meal replacement for weight control refer.

In this context, recital 43 of Regulation (EU) No 609/2013 explains that *'it is necessary that technical adaptations made pursuant to Regulation (EC) No 1924/2006, relating to health claims referring to control of body weight and made in respect of food presented as 'meal replacement for weight control', and to the conditions of use of such claims, as regulated by Directive 96/8/EC, be completed prior to the application of this Regulation.'*

1.1.2. Terms of reference

In accordance with Article 29(1) of Regulation (EC) No 178/2002, the European Commission asks EFSA for scientific advice on meal replacement for weight control. More specifically, the Commission requests EFSA to:

- advise on whether a change in the conditions of use for claims on meal replacements for weight control regarding their micronutrient composition (i.e. referring to 30% of the NRVs laid down in PART A of Annex XIII of Regulation (EU) 1169/2011 instead of the 30% of NRVs laid down in Annex I of Directive 96/8/EC) would affect the conclusions reached by the NDA Panel on its Scientific Opinion with respect to the scientific substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy

[6] Recital 43 of Regulation (EU) No 609/2013 Recital 43 of Regulation (EU) No 609/2013 explains that "Meal replacement for weight control' intended to replace part of the daily diet is considered as food for particular nutritional uses and is currently governed by specific rules under Directive 96/8/EC. However, more and more foods intended for the general population have appeared on the market carrying similar statements which are presented as health claims for weight control. In order to eliminate any potential confusion within this group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, such statements should be regulated solely under Regulation (EC) No 1924/2006 and comply with requirements set out in that Regulation. It is necessary that technical adaptations made pursuant to Regulation (EC) No 1924/2006, relating to health claims referring to control of body weight and made in respect of food presented as 'meal replacement for weight control', and to the conditions of use of such claims, as regulated by Directive 96/8/EC, be completed prior to the application of this Regulation."

[7] Commission Regulation (EU) No 432/2013 of 16 May 2012 establishing the list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, OJ L 136, 25.5.2012, p. 1

[8] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulation (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004OJ L 304, 22.11.2011, p. 18

restricted diets for weight loss) and reduction in body weight (ID 1417) and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

1.2. Interpretation of the Terms of Reference

The NDA Panel interprets this mandate as a request for scientific advice on whether or not the conclusions reached by the Panel on the scientific substantiation of health claims related to meal replacement for weight control and reduction in body weight (ID 1417) and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 could be affected by a modification of the conditions of use which is limited to the micronutrient composition of meal replacements.

The NDA Panel considers that it is out of the scope of this mandate to advise on the 'optimal' composition of meal replacements or on whether or not the conclusions reached by the Panel on the scientific substantiation of the above-mentioned claims could be affected by:

- changes in the energy content per serving as specified in EFSA's Scientific Opinion (i.e. a maximum of 250 kcal/serving).
- changes in the macronutrient composition of meal replacements as described in Annex I of Directive 96/8/EC;
- changes in target population(s) for the claims;
- new evidence on the relationship between the use of meal replacements and changes in body weight, e.g. human intervention (efficacy) studies which were not considered by the Panel for the scientific substantiation of such claims and which may have become available after the publication of EFSA's Scientific Opinion.

2. Data

The NDA Panel considered the following sources of information for this statement:

- Part A of Annex XIII of Regulation (EU) 1169/2011
- Annex I of Directive 96/8/EC
- EFSA's Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 (EFSA, 2010).

3. Assessment

In 2010, the NDA Panel adopted a Scientific Opinion on the substantiation of health claims related to meal replacement for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 (EFSA, 2010). Both claims were assessed by the Panel with a positive outcome. The scientific basis for the substantiation of these claims and the proposed conditions of use are depicted below, followed by an assessment of the impact that a change in the conditions of use limited to the micronutrient composition of meal replacements could have on the scientific substantiation of these claims.

3.1. Scientific substantiation

The food that was the subject of the health claims was 'meal replacement for weight control', which is defined in Directive 96/8/EC5 on foods intended for use in energy-restricted diets for weight reduction. Briefly, the energy provided by a meal replacement shall not be less than 840 kJ (200 kcal) and shall not exceed 1 680 kJ (400 kcal) per meal. Meal replacements for weight control shall provide not less than 25% and not more than 50% of the total energy of the product as protein, not more than 30% of the total available energy as fat, not less than 1 g of linoleic acid (in the form of

glycerides), at least 30% of the dietary reference values for adults of vitamins and minerals, and at least 500 mg of potassium per meal.

The scientific substantiation of the claim on reduction in body weight (ID 1417) was based on a number of human intervention studies conducted in overweight and obese subjects showing greater weight loss, or lower intensity of the intervention (less doctor and clinic visits, less class hours) for the same amount of weight loss, by using at least two servings daily of commercial products for the replacement of meals in the context of energy restricted diets, as compared to conventional energy-restricted diets providing the same amount of energy.

The scientific substantiation of the claim on maintenance of body weight after weight loss (ID 1418) was based on a number of human intervention studies conducted in overweight and obese subjects showing greater weight loss or lower weight gain after an intensive weight loss phase of three months by using one or two servings daily of commercial products for the replacement of meals, as compared to conventional dietary counselling for weight maintenance.

The meal replacements used in the studies considered for the substantiation of these claims usually contained up to 250 kcal/serving and generally complied with the characterisation described above except for a lower protein content expressed on energy basis (generally 18-25% energy as protein).

The proposed mechanisms by which replacing daily (conventional) meals by meal replacements for weight control could promote weight loss and weight maintenance after weight loss were the same. First, meal replacements appear to increase compliance with energy restricted programs for weight loss and weight maintenance after weight loss. This could be explained in part because they offer an easy and 'ready-to-eat' way of restricting energy intake using energy-controlled meals, in part because their (protein-rich, low-fat) macronutrient composition may induce sustained satiety to a greater extent. On the other hand, the (protein-rich, low-fat) macronutrient composition of meal replacements may induce energy inefficiency during negative energy balance by several mechanisms (increasing energy expenditure, sparing lean body mass), which may explain in part their effects on weight loss and weight maintenance after weight loss (EFSA, 2010).

In weighing the evidence, and in addition to the results of the human intervention (efficacy) studies mentioned above, the Panel took into account the biologically plausible mechanisms by which meal replacements could exert the claimed effects, mostly in relation to their controlled energy content and relatively high protein/low fat content (EFSA, 2010).

3.2. Conditions of use

In order to achieve the claimed effects, the Panel proposed that two meals should be substituted by meal replacements daily for the claim on reduction in body weight (ID 1417), and that one or two meals should be substituted with meal replacements daily for the claim on maintenance of body weight after weight loss (ID 1418). In both cases, the target population is overweight subjects in the general population (i.e. who wish to reduce their body weight and who wish to maintain their body weight after significant weight loss, respectively).

The Panel also proposed that, for both claims, a food should contain a maximum of 250 kcal/serving and comply with the specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive in order to bear the claim.

3.3. Impact of changing the micronutrient composition of meal replacements for weight control

Table 1 depicts the nutrient reference values (NRVs) for labelling purposes laid down in Annex I of Directive 96/8/EC and in Part A of Annex XIII of Regulation (EU) 1169/2011, respectively, as well as the difference (both in absolute values and as % change) in the micronutrient composition of meal replacements while considering 30% of the NRVs laid down in Part A of Annex XIII of Regulation (EU) 1169/2011, as compared to 30% of the NRVs laid down in Annex I of Directive 96/8/EC.

Switching from Directive 96/8/EC to Regulation (EU) 1169/2011 will imply some changes (increases or decreases) in the micronutrient content of meal replacements. These changes would be small (up to 13%) or absent for many micronutrients (i.e. vitamin D, thiamin, riboflavin, niacin, vitamin B6, folate,

iron, zinc, copper, selenium). The content of the remaining micronutrients (i.e. vitamin A, vitamin E, vitamin K, vitamin C, vitamin B12, biotin, pantothenic acid, chloride, calcium, phosphorus, iodine, magnesium, manganese, fluoride, chromium, molybdenum) would always be higher except for sodium, for which there are no NRVs in Regulation (EU) 1169/2011.

Taking into account that the mechanisms by which meal replacements could exert the claimed effects were mostly related to their controlled energy content and the relatively high protein/low fat content, the Panel considers that the differences in the micronutrient composition of meal replacements which would derive from changing the conditions of use from Directive 96/8/EC to Regulation (EU) 1169/2011 do not affect the scientific substantiation of health claims related to meal replacements for weight control and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 as assessed by the Panel in 2010 (EFSA, 2010).

Table 1: Nutrient reference values (NRV) and differences in the nutrient content of meal replacements for weight control assuming 30% of the NRVs laid down in Part A of Annex XIII of Regulation (EU) 1169/2011 instead of the 30% of NRVs laid down in Annex I of Directive 96/8/EC.

	NRVs		Meal replacements	
	Directive 96/8/EC	**Regulation (EC) 1169/2011**	**Difference/serving[1]**	**% difference/serving**
Vitamin A (µg RE) [2]	700	800	+30	+ 14
Vitamin D (µg)	5	5	0	0
Vitamin E (mg TE) [2]	10	12	+ 0.6	+ 19
Vitamin K (µg)	-	75	- [4]	- [4]
Vitamin C (mg)	45	80	+ 10.5	+ 77
Thiamin (mg)	1.1	1.1	0	0
Riboflavin (mg)	1.6	1.4	- 0.06	- 13
Niacin (mg NE) [2]	18	16	- 0.6	- 12
Vitamin B_6 (mg)	1.5	1.4	- 0.03	- 7
Folate (µg) [3]	200	200	0	0
Vitamin B_{12} (µg)	1.4	2.5	+ 0.33	+ 78
Biotin (µg)	15	50	+ 10.5	+ 233
Pantothenic acid (mg)	3	6	+ 0.9	+ 100
Chloride (mg)	-	800	- [4]	- [4]
Calcium (mg)	700	800	+ 30	+ 14
Phosphorus (mg)	550	700	+ 45	+ 27
Potassium (mg)	3 100	2 000	- [5]	- [5]
Iron (mg)	16	14	- 0.6	- 13
Zinc (mg)	9.5	10	+0.15	+ 5
Copper (mg)	1.1	1	- 0.03	- 10
Iodine (µg)	130	150	+ 6	+ 15
Selenium (µg)	55	55	0	0
Sodium (mg)	575	-	- [4]	- [4]
Magnesium (mg)	150	375	+ 67.5	+ 150
Manganese (mg)	1	2	+ 0.4	+ 100
Fluoride (mg)	-	3.5	- [4]	- [4]
Chromium (µg)	-	40	- [4]	- [4]
Molybdenum (µg)	-	50	- [4]	- [4]

[1] Difference per meal replacement (i.e. per serving).
[2] The units of measurement given in Regulation 1169/2011 for vitamin A (µg), vitamin E (mg) and niacin (mg) refer to retinol equivalents (RE), tocopherol equivalents (TE) and niacin equivalents (NE), respectively, as in Directive 96/8/EC.
[3] The NRVs given in Regulation 1169/2011 for 'folic acid' actually refer to folate, as in Directive 96/8/EC.
[4] Differences have not been calculated for nutrients for which NRVs are not given either in Directive 96/8/EC or Regulation 1169/2011.
[5] A minimum of 500 mg of potassium per meal replacement (i.e. per serving) was required in Directive 96/8/EC, which is below 30% of either reference value (i.e. 3100 in Directive 96/8/EC and 2000 mg in Regulation 1169/2011, respectively).

4. Conclusions

The Panel concludes that the differences in the micronutrient composition of meal replacements which would derive from changing the conditions of use from Directive 96/8/EC to Regulation (EU) 1169/2011 do not affect the scientific substantiation of health claims related to meal replacements for weight control and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006, as assessed by the Panel in 2010 (EFSA, 2010).

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(2):1466, 19 pp. doi:10.2903/j.efsa.2010.1466

Abbreviations

NRV	Nutrient reference values